



TFW 1636

PTO/SB/21 (09-04)  
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/574,167
Filing Date	March 29, 2006
First Named Inventor	BUSH et al.
Art Unit	1636
Examiner Name	TBD
Attorney Docket Number	8028-007-US

### ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers  <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC  <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences  <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)  <input type="checkbox"/> Proprietary Information  <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): -Copies of References -Self-Addressed, Stamped Postcard
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Remarks

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Catalyst Law Group, APC		
Signature			
Printed name	Michael B. Farber, Ph.D, Esq		
Date	July 12, 2006	Reg. No.	53,150

### CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

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Typed or printed name	Sara Hare	Date	July 12, 2006

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	)	Examiner: To Be Assigned
	)	
Bush et al.	)	Group Art Unit: 1636
	)	
Serial No.: 10/574,176	)	Docket No.: 8028-007-US
	)	
Filed: March 29, 2006	)	Date Mailed: July 12, 2006
	)	
For: USE OF CELL LINES TO	)	
PRODUCE ACTIVE THERAPEUTIC	)	
PROTEINS	)	

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop: Information Disclosure Statement  
Honorable Commissioner for Patents  
P.O. Box 1450  
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Dear Sir:

This document is a Supplemental Information Disclosure Statement to the above-cited patent application.

Attached is at least one form PTO/SB/08A/B listing documents believed relevant to the subject application. The submission of the following information is not intended, nor should it be construed, to constitute an admission that any patent, article, or other information referred to herein is "prior art" unless specifically designated as such. In accordance with 37 C.F.R. § 1.97(b), the filing of this information shall not be construed to mean that a search has been made or that no other material information may exist. Neither should its submission be construed to indicate that a thorough search should not be conducted by the Examiner.

It is believed that this disclosure complies with the requirements of 37 C.F.R. § 1.96, § 1.97, and § 1.98 and the Manual of Patent Examining Procedures § 707.05(b). If for some reason the Examiner considers otherwise, it is respectfully requested that the undersigned be telephoned at (858) 450-0099 x302 so that any deficiencies can be remedied.

This Supplemental Information Disclosure Statement is being submitted before the mailing date of an Office Action on the merits for the above-identified patent application. Accordingly, no fee is due for the filing of this Information Disclosure Statement under 37 C.F.R. § 1.97(b)(2).

A copy of each document is enclosed, except for issued United States patents and published United States patent applications pursuant to 37 C.F.R. § 1.98(a)(2)(ii). Some of the documents may have markings thereon. No significance is to be attached to the markings. These documents are not necessarily analogous art. Additionally, the order of the following documents is to be accorded no particular import, as the order thereof is completely fortuitous.

It is respectfully requested that these documents be: (1) fully considered by the Patent and Trademark Office during the prosecution of this application; and (2) represented on any patent which may issue on the application. Applicant respectfully requests that copies of the forms PTO/SB/08A/B, as considered and initialed by the Examiner, be returned with the next communication.

A publication, F.P. Guengerich, "Cytochrome P450: What Have We Learned and What Are the Future Issues?" Drug Metab. Rev. 36: 159-197 (2004).

A publication, N. Kobayashi et al., "Improvement in the Differentiated Hepatic Phenotype of Immortalized Human Hepatocytes by Adenovirus Mediated p21 Gene Transfer," ASAIO J. 48: 355-359 (2002).

A publication, A. Paulus, "The Reengineering of Drug Development in the Genomics and Proteomics Era," Am. Clin. Lab. 5: 9-10 (2001).

A publication, T.M. Donohue et al., "Synthesis and Secretion of Plasma Proteins by the Liver" in Hepatology: A Textbook of Liver Disease (D. Zakim & T.D. Boyer, eds, W.B. Saunders, Philadelphia, 1990), pp. 124-137.

A publication, M.S. Rangel-Frausto et al., "The Natural History of the Systemic Inflammatory Response Syndrome (SIRS): A Prospective Study," JAMA 273: 117-123 (1995).

A publication, F. Bost et al., "Inter-Alpha-Trypsin Inhibitor Proteoglycan Family-a Group of Proteins Binding and Stabilizing the Extracellular Matrix," Eur. J Biochem. 252: 339-346 (1998).

A publication, S. Yang et al., "Administration of Human Inter-Alpha-Inhibitors Maintains Hemodynamic Stability and Improves Survival During Sepsis," Crit. Care Med. 30: 617-622 (2002).

A publication, M. Murray, "P450 Enzymes: Inhibition Mechanisms, Genetic Regulation and Effects of Liver Disease," Clin. Pharmacokinetics 23: 132-146 (1992).

A publication, K.E. Thummel & G.R. Wilkinson, "In Vitro and In Vivo Drug Interactions Involving Human CYP 3A," Ann. Rev. Pharmacol. Toxicol. 38: 389-430 (1998).

A publication, S. M. Cascio, "Novel Strategies for Immortalization of Human Hepatocytes," Artificial Orgs. 25: 529-538 (2001).

A publication, T. Kuroki & N. Huh, "Why Are Human Cells Resistant to Malignant Cell Transformation in Vitro?," Jpn. J. Cancer Res. 84: 1091-1100 (1993).

A publication, F.L. Graham et al., "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5," J. Gen. Virol. 36:59-72 (1977).

A publication, H. Zur Hausen, "Oncogenic Herpes Viruses" in: J. Tooze ed., DNA Tumor Viruses ( Rev. Ed. 2, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, N.Y., 1981), pp 747-798.

A publication, A.J. Dorner & R.J. Kaufman, "Analysis of Synthesis, Processing, and Secretion of Proteins Expressed in Mammalian Cells" in Gene Expression Technology (D.V. Goeddel, ed., Academic Press, San Diego, 1991), pp. 577-598.

A publication, L.M. Fink & S.M. Clarke, "Monoclonal Antibodies as Diagnostic Reagents for the Identification and Characterization of Human Tumor Antigens," Prog. Clin. Pathol. 9:121-133 (1984).

A publication, C.R. Cantor & C.L. Smith, "Genomics: The Science and Technology Behind the Human Genome Project" (John Wiley & Sons, 1999), pp. 119-120.

A publication, K.B. MacDonald & W.H. Bruce, "A Minicolony Assay for the Viability of Mammalian Cells *in Vitro*," Exp. Cell. Res. 50:471-473 (1968).

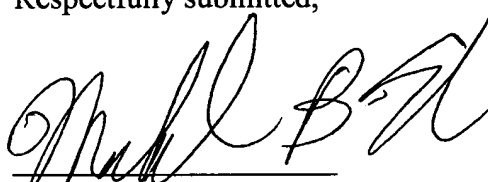
A publication, E.J. Stanbridge et al, "Human Cell Hybrids: Analysis of Transformation and Tumorigenicity," Science 215:252-259 (1982).

A publication, G.T. Tucker et al., "Optimizing Drug Development: Strategies to Assess Drug Metabolism/Transporter Interaction Potential – Toward a Consensus," Pharmaceutic. Res. 18: 1071-1080 (2001).

A publication, J.T. Moore & S.A. Klierer," Use of the Nuclear Receptor PXR to Predict Drug Interactions," Toxicology 153: 1-10 (2000).

Respectfully submitted,

Date: July 12, 2006

  
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Reg. No.: 32,612

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/574,167
Filing Date	March 29, 2006
First Named Inventor	BUSH et al.
Art Unit	1636
Examiner Name	TBD
Attorney Docket Number	8028-007-US

Sheet	1	of	2
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**NON PATENT LITERATURE DOCUMENTS**

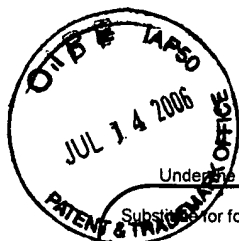
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		F.P. GUENGERICH, "Cytochrome P450: What Have We Learned and What Are the Future Issues," Drug Metab. Rev. 36:159-197 (2004).	
		N. KOBAYASHI et al., "Improvement in the Differentiated Hepatic Phenotype of Immortalized Human Hepatocytes by Adenovirus Mediated p21 Gene...", ASAIO J. 48: 355-359 (2002).	
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		T.M. DONOHUE et al., "Synthesis and Secretion..." in Hepatology: A Textbook of Liver Disease (D. Zakim & T.D. Boyer, eds, W.B. Saunders, Philadelphia, 1990), pp. 124-137.	
		M.S. RANGEL-FRAUSTO et al., "The Natural History of the Systemic Inflammatory Response Syndrome (SIRS): A Prospective Study," JAMA 273: 117-123 (1995).	
		F. BOST et al., "Inter-Alpha-Trypsin Inhibitor Proteoglycan Family-a Group of Proteins Binding and Stabilizing the Extracellular Matrix," Eur. J Biochem. 252: 339-346 (1998).	
		S. YANG et al., "Administration of Human Inter-Alpha-Inhibitors Maintains Hemodynamic Stability and Improves Survival During Sepsis," Crit. Care Med. 30: 617-22 (2002).	
		M. MURRAY, Clin. Pharmacokinetics 23: 132-146 (1992).	
		K.E. THUMMEL & G.R. WILKINSON, "In Vitro and In Vivo Drug Interactions Involving Human CYP 3A," Ann. Rev. Pharmacol. Toxicol. 38: 389-430 (1998).	
		S. CASCIO, "Novel Strategies for Immortalization of Human Hepatocytes," Artificial Orgs. 25: 529-538 (2001).	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Sheet 2 of 2

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		KUROKI & N. HUH, "Why Are Human Cells Resistant to Malignant Cell Transformation in Vitro?," Jpn. J. Cancer Res. 84: 1091-1100 (1993).	
		F.L. GRAHAM et al., "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5," J. Gen. Virol. 36:59-72 (1977).	
		H. ZUR HAUSEN, "Oncogenic Herpes Viruses" in: J. Tooze ed., DNA Tumor Viruses ( Rev. Ed. 2., Cold Spring Harbor Laboratory Press, Cold Spring Harbor, N.Y., 1981), pp 747-798.	
		A.J. DORNER & R.J. KAUFMAN, "Analysis of Synthesis...", in Gene Expression Technology (D.V. Goeddel, ed., Academic Press, San Diego, 1991), pp. 577-598.	
		FINK et al., Prog. Clin. Pathol. 9:121-133 (1984).	
		C.R. CANTOR & C.L. SMITH, "Genomics: The Science and Technology Behind the Human Genome Project" (John Wiley & Sons, 1999), pp. 119-120.	
		MACDONALD et al, Exp. Cell. Res. 50:417 (1968).	
		STANBRIDGE et al, Science 215:252-259 (1982).	
		G.T. TUCKER et al., "Optimizing Drug Development: Strategies to Assess Drug Metabolism/Transporter Interaction Potential – Toward...", Pharmaceutic. Res. 18: 1071-1080 (2001).	
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